

## REMARKS

Claims 13-18 and 24-30 are pending. Claims 13, 18 and 28 are independent.

### **Rejections of Claims 13-18 and 24-29**

Claims 13-18 and 27-29 stand rejected under 35 U.S.C. § 102(b), with the Office Action relying on U.S. Patent No. 3,851,650 to Darling. Claims 24-26 stand rejected under 35 U.S.C. § 103, with the Office Action relying on the Darling '650 patent and U.S. Patent No. 4,953,561 to Guirguis. The Applicant respectfully requests reconsideration of those rejections in view of the following remarks.

## **Applicant's Invention and Example Embodiments**

Applicant's invention is directed to a device for modifying a fluid moving through a vessel prior to the ejection of the fluid from the vessel into the body of a patient. An example of an embodiment within the scope of at least the independent claims is illustrated in Applicant's Figure 1, reproduced below:

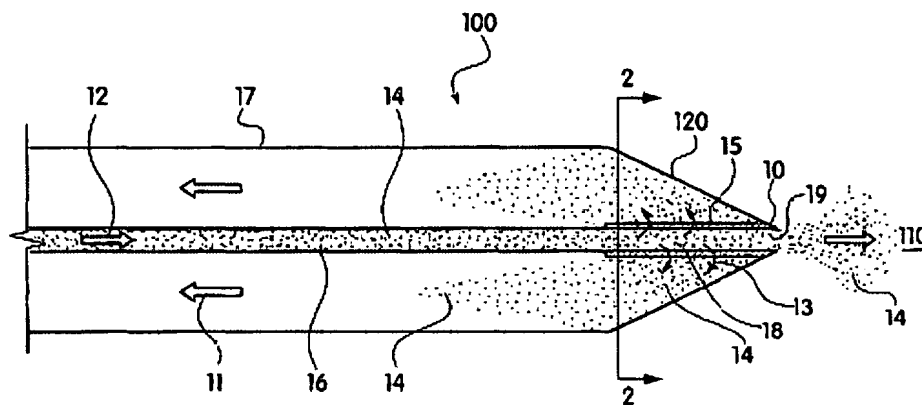


FIG. 1

In this embodiment, the vessel is a catheter 100 comprising a first lumen 16, a second lumen 17, and an exit orifice 19 located at a distal end of the first lumen. A mixing or modification chamber 18 is positioned within the first lumen 16 proximal to the exit orifice 19. The arrows 13 show the flow of compounds through a selectively permeable membrane 15 in a passageway located proximal to the exit orifice 19, the passageway being positioned between the chamber 18 and the second lumen 17. The passageway fluidly connects the chamber 18 to the second lumen 17, and the selectively permeable membrane 15 is positioned to selectively pass compounds through the passageway between the chamber 18 and the second lumen 17.

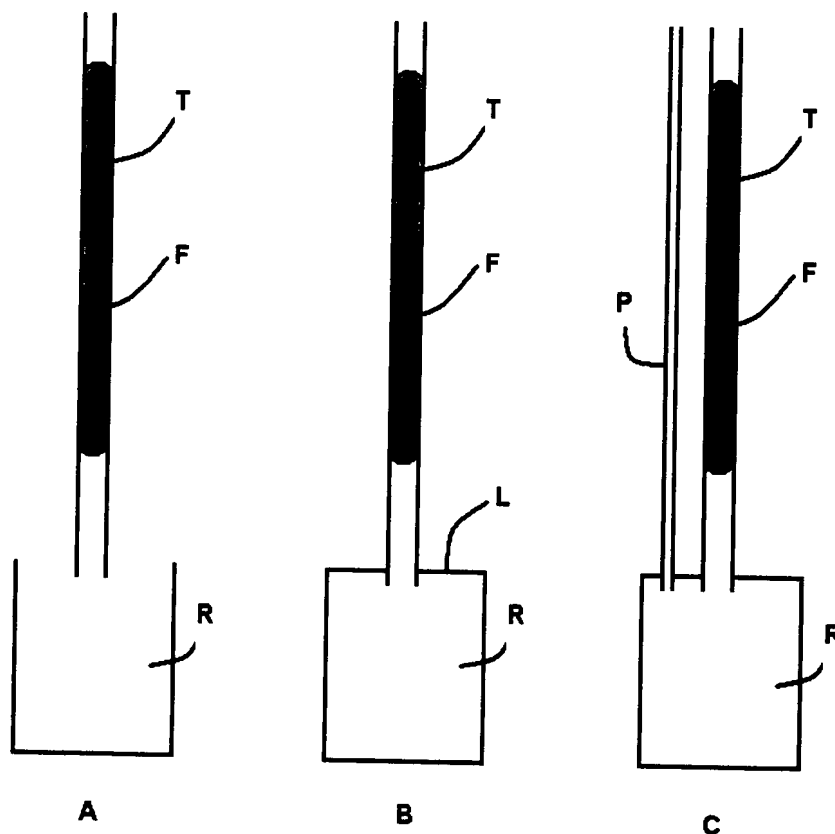
As an example of a use of this embodiment, fluid including a therapeutic agent and a solvent may be transported through the first lumen 16 from a proximal end of the catheter 100 to a distal end of the catheter 100. Before reaching the exit orifice 19, the fluid passes into the fluid mixing or modification chamber 18 located within the first lumen 16. Because the solvent of the fluid is able to pass through the selectively permeable membrane 15, solvent is drawn away from the fluid in the chamber 18 and into the second lumen 17. Thus, the amount of solvent in the fluid is lowered prior to delivery of the fluid through the exit orifice 19 to the patient. While this example involves extraction of a compound from the fluid while the fluid is in the fluid modification chamber, the device may also be used for addition of a compound to the fluid while the fluid is in the fluid modification chamber.

### **The Darling '650 Patent**

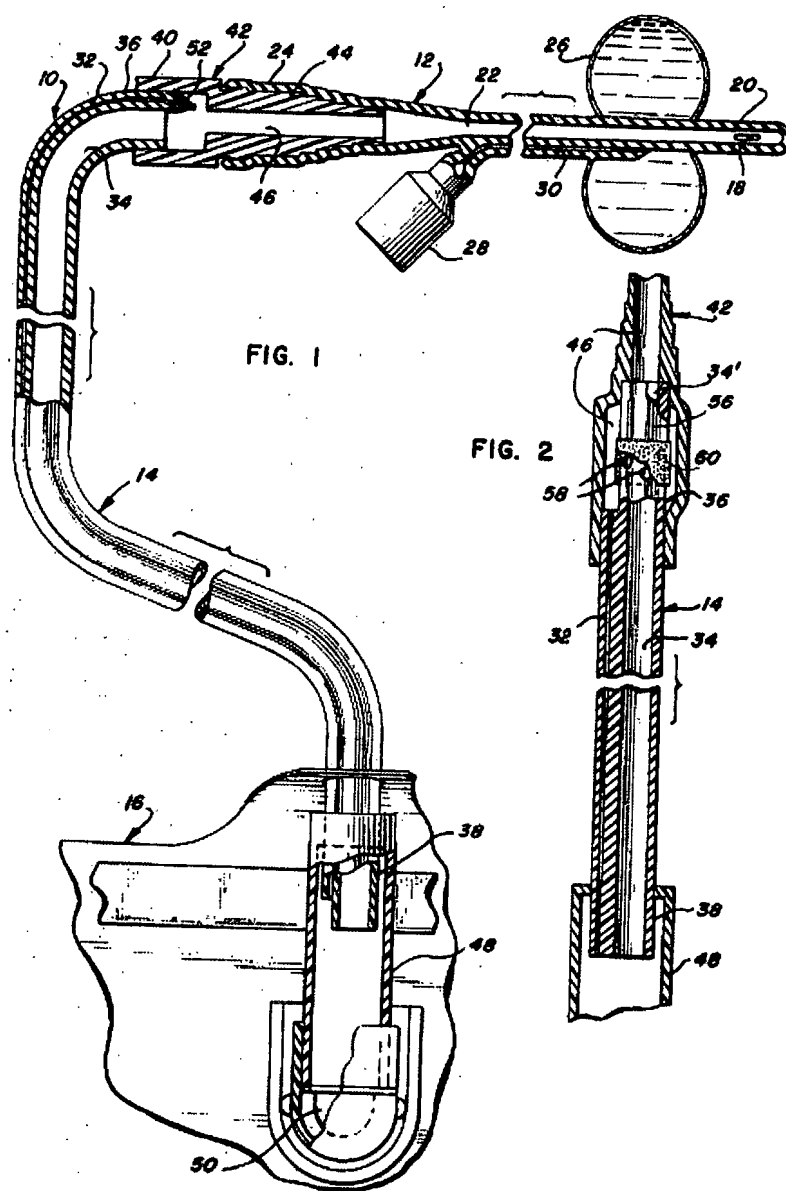
The Darling '650 patent is directed to a device that is for a completely different purpose as compared to Applicant's invention. Accordingly, the differences between Applicant's claims and the Darling '650 patent are numerous.

While Applicant's invention is a device for supplying fluid into the body of a patient, the Darling '650 is for draining fluid from a patient. According to the Darling '650 patent, it attempts to address the problem of providing a "closed" drainage system to prevent the introduction of infection into the body while at the same time overcoming the problem of negative air pressure that can stop fluid flow. (Darling, col. 1, lines 17-36).

As an analogy, if one considers fluid F flowing down a tube T into a reservoir R as illustrated in the Figures A through C below, the Darling problem is readily apparent. In A, the top of the reservoir is open, so air can escape, and the fluid F can flow down the tube. In B, the top of the reservoir is closed with a lid L, for example to prevent infection. This closure causes air to be trapped, thereby stopping fluid flow. In C, a supplemental air pressure release tube P is provided to allow the air to escape as fluid flows into the reservoir, thereby overcoming the issue of the negative air pressure, and enabling fluid flow.



The Darling device is illustrated below. Fluid drains from the patient into drainage eye 18. The flow goes from there out of the patient through lumen 34 into drip chamber 48. To relieve air pressure, the Darling device has another lumen 32, for the passage of air from the drip chamber 48 back up to a point near the inlet end of lumen 34.



In Figure 1, a valve means 52 is positioned at the top of lumen 32 to allow air to go out of lumen 32 but to prevent fluid from entering lumen 32. Figure 2 shows an alternative embodiment for achieving this same objective. In Figure 2, the tube has a section 56

surrounding a portion 34' of the lumen 34. The tube section 56 has a plurality of apertures 58. An "air-pervious, fluid-impervious" filter 60 covers the apertures 58. The filter 60 thus allows air to exit lumen 32, but prevents fluid from entering lumen 32.

The Darling patent describes the filter 60 precisely this way. It says:

Thus, liquid is confined in the lumen portion 34' by the filter 60, while air is permitted to pass from the lumen 32 through the filter 60 and apertures 58 to break negative air pressure which may develop in the lumen 34 and lumen portion 34'.

Darling, col. 3, lines 33-37.

The Applicant respectfully submits that there are a number of differences between Applicant's claimed invention and the Darling device. With respect to claim 13, Applicant's device is for ejection of fluid "into the body of a patient," while the Darling device drains fluid from the body. Applicant's device of claim 13 requires "an exit orifice located at a distal end of the first lumen." The Office Action does not identify what structure in Darling is considered to be the "exit orifice." The Office Action equates the lumen 34 of Darling with the first lumen; if that is so, then the exit orifice must be where fluid exits lumen 34, which is into Darling's drip chamber 48. However, Applicant's claim 13 requires "a mixing chamber positioned within the first lumen proximal to the exit orifice, the mixing chamber in communication with the exit orifice." The Office Action equates the tube section 56 of Darling with the mixing chamber, but that tube section 56 is nowhere near the exit end of the lumen 34 (i.e., nowhere near drip chamber 48). Similarly, Applicant's claim 13 requires "a passageway located proximal to the exit orifice." The Office Action equates the apertures 58 of Darling with the passageway, but again those apertures 58 are nowhere near the exit end of the lumen 34. Applicant's claim 13 also requires that the passageway is "fluidly connecting the mixing chamber to the second lumen, the passageway containing a selectively permeable membrane positioned to selectively

pass compounds through the passageway between the mixing chamber and the second lumen.”

However, in Darling, the filter 60 only permits the passage of air between lumen 32 and lumen 34. It does not meet the requirement of “fluidly connecting . . . to selectively pass compounds.”

With respect to claim 14, Darling does not disclose “a third lumen, the third lumen in fluid communication with the mixing chamber.” With respect to claim 15, Darling does not disclose “a vacuum source in fluid communication with the second lumen” or “a resin positioned within the second lumen, the resin adapted to trap and retain compounds passing through the selectively permeable membrane and resident within the second lumen.” With respect to claim 16, Darling does not disclose a selectively permeable membrane being “adapted to extract a solvent from fluid in contact with the selectively permeable membrane.” That is contrary to Darling, where the filter only allows air to pass. With respect to claim 17, Darling does not disclose the fluid being a “therapeutic.” Again, that is contrary to Darling, which is for the drainage of fluid from the body.

Claim 18 is patentable over Darling for reasons similar to those given above with respect to claim 13. In addition, claim 18 requires that “the first lumen and the second lumen are concentric about one another and share a longitudinal axis.” This is not met by the lumens 32 and 34 in Darling, which are side by side, not concentric.

Claim 28 is also patentable over Darling. Claim 28 requires a catheter “for delivering a fluid inside the body of a patient” comprising “a first lumen for transporting the fluid from a proximal end of the catheter to a distal end of the catheter, the first lumen comprising an exit orifice at the distal end of the catheter through which the fluid is discharged to the patient.” As stated above, the Darling device is designed for drainage of fluid from a patient. Claim 28 further states that the catheter comprises “a fluid modification chamber located within the first

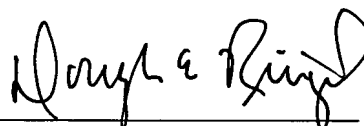
lumen proximal to the exit orifice,” but again, the structure that the Office Action identifies as the mixing chamber of Darling (tube section 56) is nowhere near the exit orifice of the structure that the Office Action identifies as the first lumen (i.e., the exit end of lumen 34 at its entrance to drip chamber 48). Claim 28 also requires a selectively permeable membrane “positioned to selectively pass compounds through the passageway between the fluid modification chamber and the second lumen, thereby modifying the fluid prior to the fluid being discharged through the exit orifice.” In Darling, the filter 60 is only for the passage of air, and to prevent passage of fluid. It does not “selectively pass compounds . . . thereby modifying the fluid prior to the fluid being discharged through the exit orifice.” Similarly, with respect to claim 29, the filter 60 in Darling is not “adapted to extract a solvent from the fluid while the fluid is in the fluid modification chamber.”

### CONCLUSION

For the foregoing reasons, the Applicant respectfully requests reconsideration of this application. While no fees are believed to be due, the Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

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